CQV, QA & CAPEX Project Engineering

Profiles Catalog

CQV Profiles

CQV Profiles

C. J.

CQV Engineer | Available now

📍 **Location**: Switzerland (mobility within Europe)
🩹 **Experience**: 5+ years
🌐 **Languages**: English (Native)

💼 EXPERTISE SUMMARY

CQV professional with a strong foundation in validation engineering and bioprocess operations. Proven experience in executing qualification protocols (IQ/OQ/PQ), coordinating FAT/SAT, managing deviations, and supporting GMP inspections. Dual background in operational execution and regulatory compliance within biotech and pharma environments.

🔧 KEY SKILLS & TECHNOLOGIES

- CQV: DQ, IQ, OQ, PQ, PPQ
- FAT/SAT coordination
- Risk assessments & deviation handling
- Data integrity & audit readiness
- Regulatory standards: GAMP, cGMP, Annex 1
- Tools: DeltaV, Kneat, MES Syncade, SAP, LIMS
- Lean tools: 5S, RCA, continuous improvement

🏭 INDUSTRY EXPERIENCE

- Pharma (small and large molecule)
- Biotech manufacturing (ATMPs, sterile)
- Validation engineering & QA support
- Commissioning of GMP utilities and equipment

🎓 EDUCATION

- MSc in Pharmaceutical Analysis – Queen's University Belfast
- BSc in Pharmaceutical & Biomedical Chemistry – Maynooth University

📈 PROJECT HIGHLIGHTS

Led execution of commissioning and qualification for GMP utilities and cleanroom systems
SME during smoke studies and airflow visualization audits
Delivered end-to-end validation for new equipment onboarding and tech transfer initiatives
Supported inspection readiness and acted as primary stakeholder liaison

H. H.

CQV & Manufacturing Specialist | Available now

📍 **Location**: Switzerland
🧪 **Experience**: 8+ years
🌐 **Languages**: French (Native), English (Fluent)

💼 EXPERTISE SUMMARY

Experienced CQV and Manufacturing professional with a strong background in biotech and pharmaceutical environments. Skilled in commissioning, qualification, process validation, GMP manufacturing, and inspection readiness. Brings operational depth and cross-functional coordination from roles in QA, production, and tech transfer.

🔧 KEY SKILLS & TECHNOLOGIES

- CQV: DQ, IQ, OQ, protocol execution
- Process & cleaning validation
- GMP inspection & audit preparation
- Bioreactor setup (CIP/SIP) and cell culture
- SOP & batch record authoring and review
- Tools: Kneat, DeltaV, TrackWise, LIMS, Syncade
- Standards: GMP, cGDP, ALCOA, ISO/IEC 17025

📈 PROJECT HIGHLIGHTS

- Supported multiple GMP audits and regulatory inspections (FDA, Partners)
- Executed end-to-end CQV and cleaning validation using Kneat
- Coordinated cross-functional activities in QC, automation, QA, and manufacturing
- Participated in tech transfer for Phase 3 biotech production
- Developed SOPs and trained peers on best practices in cleanroom environments

🏭 INDUSTRY EXPERIENCE

- Biotech (clinical & commercial)
- Drug substance manufacturing (upstream & downstream)
- Quality Assurance & inspection support
- Equipment qualification & facility start-up

🎓 EDUCATION

- BSc in Life Technologies – HES-SO Valais, Switzerland
- Diplomas in Laboratory Technology – Lausanne & TAFE Australia
- ARIAQ – Equipment Qualification & Method Validation
- Lean Six Sigma Foundations
- Certified in Quality Management & Inspection Readiness (2024)

P. R.

CQV & Quality Compliance Specialist | Available now

📍 **Location**: Switzerland
🧫 **Experience**: 7+ years
🌐 **Languages**: English, Spanish

💼 EXPERTISE SUMMARY

Pharmacist with extensive experience across equipment qualification, process validation, and quality assurance in GMP environments. Skilled in supporting global pharma clients with regulatory compliance, audit readiness, and cross-functional CQV coordination. Brings agility and structure to fast-moving pharmaceutical and biotech operations.

🔧 KEY SKILLS & TECHNOLOGIES

- Equipment & utility qualification
- Risk analysis & deviation/CAPA management
- Regulatory audit support (FDA, GxP, GMP)
- Document review & SOP enforcement
- Tools: Kneat, GDocP, incident & punch closeout systems
- Standards: FDA, ICH Q3D, GMP, GxP

🏭 INDUSTRY EXPERIENCE

- Large-scale biotech (facility & service qualification)
- Pharma labs (compliance and CAPA systems)
- GxP consulting and audit preparation
- QA document control and employee training

🎓 EDUCATION

- MSc in Pharmaceutical Industry & Parapharmacy – CESIF
- Pharmacy Degree – Universidad Complutense de Madrid

📈 PROJECT HIGHLIGHTS

- Managed CQV execution at Takeda: coordinating providers and facility readiness
- Acted as GxP consultant for multiple pharma audits and validation projects
- Led QA documentation review and deviation management at Italfarmaco & ROVI
- Supported the Lonza Visp site with component verification and incidence closure using Kneat

P. C.

CQV & CSV Consultant | Available now

📍 **Location**: Switzerland
🧪 **Experience**: 5+ years
🌐 **Languages**: Polish (Native), English (Fluent), Spanish (Proficient)

💼 EXPERTISE SUMMARY

Multidisciplinary CQV and CSV specialist with hands-on experience in commissioning, qualification, cleanroom validation, and computer system validation for biotech and pharmaceutical environments. Strong understanding of regulatory frameworks including FDA, GAMP, and CFR 21 Part 11. Skilled in installation verification, risk assessment, and managing deviation workflows for critical GMP equipment and cleanroom operations.

🔧 KEY SKILLS & TECHNOLOGIES

- IQ/OQ/PQ protocol development & execution
- Equipment qualification (CTUs, clean utilities, filtration skids, autoclaves)
- SAT/FAT testing, cleanroom classification, calibration
- CSV & data integrity (21 CFR Part 11, audit trails)
- Risk assessment (FMEA), deviation writing & closure
- Tools: Kneat Gx, Ellab, DeltaV, HPLC, GMP tracking platforms
- Standards: GMP, GxP, ALCOA, GAMP, ISO 9001, ISO/IEC 17025

🏭 INDUSTRY EXPERIENCE

- Pharmaceutical & biotech facilities (Europe-wide)
- Cleanroom validation & temperature mapping
- Filling lines & utilities (purified water, WFI, tunnels, incubators)
- Compliance remediation & audit support

🎓 EDUCATION

- MSc in Biotechnology – University of Life Sciences
- BSc in Food Technology & Human Nutrition – University of Life Sciences
- Lean Six Sigma Yellow Belt (2024)
- Capgemini L1 & L2 Life Sciences Industry Certifications
- FMEA Specialist Certification – AIGPE (2024)

📈 PROJECT HIGHLIGHTS

- Led CQV protocol execution at Capgemini across CIP systems and DSP equipment
- Delivered FDA remediation projects, including risk assessment and cleanroom testing
- Executed SAT/OQ protocols for complex filling line machinery and utilities
- Supported global pharma clients in full CSV lifecycle activities with validated documentation workflows

S. D.

Senior CQV & QA Expert | Available now

📍 **Location**: Switzerland (on-site preferred)
🧪 **Experience**: 25+ years
🌐 **Languages**: French (Native), English (Intermediate)

💼 EXPERTISE SUMMARY

Senior expert in CQV and QA with over two decades of experience in the pharmaceutical and biotechnology sectors. Specializing in clean utilities, process validation (API, USP/DSP), cleaning validation, and quality system oversight. Highly experienced in leading commissioning and qualification activities for new facilities, equipment revamping, and regulatory audits. Known for pragmatic execution, cross-functional leadership, and QA rigor.

🔧 KEY SKILLS & TECHNOLOGIES

- CQV: FAT/SAT, IV, OQ, PQ
- Clean utilities: Purified Water, WFI, Pure Steam, Nitrogen, Process Air
- Validation strategy (API, biotech, USP/DSP)
- Cleaning validation & cleanroom qualification
- QA oversight: deviation, CAPA, punch/incident closure
- Tools: Kneat, Veeva, TrackWise, SAP, DMS
- Standards: cGMP, 21 CFR, ISO EN285, ISO 8573-1, ASTM 2500-07

🏭 INDUSTRY EXPERIENCE

- Greenfield and brownfield projects (API, biotech, vaccines)
- Equipment qualification for bulk production and cleanrooms
- Clean utilities installation and functional verification
- QA project leadership and validation strategy definition

🎓 EDUCATION

- Superior Technician in Pharmaceutical Industry – IMT Paris

📈 PROJECT HIGHLIGHTS

- Led clean utilities and process equipment qualification for a new API plant at Lonza
- Defined validation process strategy for biotech manufacturing (USP/DSP)
- Acted as QA SME on cleaning validation and quality system readiness at Incyte
- Delivered end-to-end CQV for bulk vaccine facilities at GSK
- Supported commissioning and loop validation of air, steam, and nitrogen systems in line with EN/ISO standards

QA Profiles

A. P.

Senior Quality, CSV & Microbiology Expert | Available now

📍 **Location**: Switzerland (on-site & hybrid projects)
🧪 **Experience**: 30+ years
🌐 **Languages**: Dutch (Native), English (Native), German (Native)

💼 EXPERTISE SUMMARY

Senior professional with 30+ years of experience in the pharmaceutical industry across Quality Assurance, Computer System Validation, and Microbiology. Brings extensive expertise in GMP compliance, sterile manufacturing, deviation/CAPA management, and inspection readiness. A certified Biosafety Officer and experienced people manager, capable of structuring complex environments, leading investigations, and improving quality systems in highly regulated environments.

🔧 KEY SKILLS & TECHNOLOGIES

- Deviation & CAPA management (TrackWise, COMET)
- CSV (GAMP5, SDLC, GMP data integrity)
- QA oversight in sterile manufacturing
- Microbiology: endotoxins, bioburden, cleanroom monitoring
- Document control, audit preparation & inspection readiness
- Leadership in training, team development, and project coordination
- Tools: LIMS, SAP, DMS, Honeywell TrackWise, lisa.lims, PHARMA-CBV
- Standards: GMP, GxP, GAMP, ALCOA, FDA, ISO

🏭 INDUSTRY EXPERIENCE

- Global pharma/biotech environments (sterile, non-sterile, vaccines)
- QA lead roles in validation, microbiology, and CSV
- Expert-level support in audits, complaints, hygiene concepts, and system inspections
- Proven success in complex regulatory environments (FDA, EU)

🎓 EDUCATION

- Lab Technician Microbiology – IHBO Eindhoven
- Over 20 advanced certifications incl. GMP compliance, hygiene, CSV, and audit readiness (Concept Heidelberg, Biomérieux, Biotest, Charles River)

📈 PROJECT HIGHLIGHTS

- Acted as QA Nonconformance Coordinator at Janssen (2024), leading site-wide compliance efforts
- Managed microbiology QC improvements and SOP systems at Lonza and Legacy Pharmaceuticals
- Oversaw CSV activities for packaging/serialization systems at MSD under GAMP5
- Developed and delivered hygiene concepts and staff training as BSO & Hygiene Officer
- Supported multiple inspections with audit documentation and real-time quality issue handling

A. G. G.

Senior Quality, CSV & Microbiology Expert | Available now

📍 **Location**: Switzerland (on-site & hybrid projects)
🧪 **Experience**: 9+ years
🌐 **Languages**: Spanish (Native), English (Fluent), German & Italian (Basic)

💼 EXPERTISE SUMMARY

Multifaceted pharmaceutical professional with over 9 years of experience in Quality Assurance, CQV, and Operational Excellence across top-tier organizations. Proven ability to lead teams, resolve complex QA topics, and drive quality across commissioning, qualification, and validation activities. Experienced with both operational execution and strategic leadership — including management of quality teams and direct QA responsibility for GxP-compliant environments.

🔧 KEY SKILLS & TECHNOLOGIES

- CQV QA management for direct/non-direct impact systems
- GMP, GDP, ALCOA++ compliance & documentation review
- Regulatory expertise (FDA, ICH Q8/Q9/Q10, ASTM E2500)
- Complaint handling, deviation management, CAPA
- Software tools: Kneat Gx, TrackWise, Veeva Vault QMS, SAP, DMS

🏭 INDUSTRY EXPERIENCE

- Biopharmaceutical production (Lonza, Moderna)
- Vaccine QA & complaints management (Moderna)
- GMP compliance in drug manufacturing (Eli Lilly, Bayer)
- Medical information & affairs (Roche)
- Quality systems implementation & audit support (Azierta, SHL Medical)

🎓 EDUCATION

- MSc in Pharmacy + MSc in Pharmaceutical Industry
- Certified in Project Management (UC Berkeley)
- Lean Six Sigma Green Belt
- Trained in ALCOA++, ICH Q9, ICH Q10, FDA compliance

📈 PROJECT HIGHLIGHTS

- QA Lead for CQV activities at Lonza Visp for multiple systems including reactors, HVAC, water and gas systems, with final approval responsibilities in Kneat
- Handled over 400 vaccine quality complaints globally at Moderna, and designed internal QA training sessions across Europe
- Led the Bacthera Task Force QA team, overseeing remediation activities on validation documentation and ensuring data integrity
- People Manager Coordinator at Capgemini for QA consultants, focusing on performance, conflict resolution, and career development

A. P. D.

Senior QA & Regulatory Expert | Available now

📍 **Location**: Switzerland (on-site & hybrid projects)
🧪 **Experience**: 20+ years
🌐 **Languages**: French (Native), English (Fluent), German & Portuguese (Proficient)

💼 EXPERTISE SUMMARY

A senior QA consultant with 20 years of multidisciplinary experience across pharmaceuticals, medical devices, IVD, and CRO environments. Expert in QA and QMS across the full product lifecycle, with a strong background in validation, regulatory submissions, supplier qualification, and internal audits. Proven track record of delivering compliance in both GxP and ISO 13485 environments, with hands-on experience in both product and process QA, QC lab oversight, and regulatory affairs.

🔧 KEY SKILLS & TECHNOLOGIES

- QA/QMS for pharma & medical devices (class I & II)
- Validation: analytical methods, equipment (IQ/OQ/PQ), software (IEC 62304)
- Batch release (EU, US, OUS markets)
- Regulatory compliance: USP, Ph. Eur., JP, FDA, ISO 13485, ISO 14155
- Change control, CAPA, deviation management, risk assessment (FMEA, RACT)
- Tools: Veeva, TrackWise, SAP, LIMS, JIRA, POLARION, Microsoft Office

🏭 INDUSTRY EXPERIENCE

- Biologics and vaccine production (Lonza, Moderna, Ferring)
- Diagnostics, biosensors, and auto-injectors (SHL Medical, Abionic, Bracco)
- Clinical and pre-clinical studies (CHUV, Aginko)
- CRO and bioanalytics (Glenmark, Ayanda, Manteia)

🎓 EDUCATION

- PhD, EPFL – Life Sciences
- Chemical Engineering, EPFL
- Certified in Internal Auditing, Clinical GCP (CITI), Risk Analysis (FMEA, RACT), Deviation/CAPA, and more

📈 PROJECT HIGHLIGHTS

- Led QA document review for equipment commissioning and qualification at Lonza ORCA project (2024–25)
- Acted as batch release manager for Moderna's Covid-19 vaccines across global markets
- Built and validated full QC lab infrastructure at Abionic, covering method validation and GMP compliance
- Reviewed global pharmacopeia alignment for QC raw materials at Merck and Ferring
- Oversaw QA for software development under IEC 62304 for Bracco contrast injectors
- Extensive track record in supplier audits, regulatory inspection readiness, and change control leadership

F. C.

Senior QA Leader | Available now

📍 **Location**: Switzerland (on-site & hybrid projects)
🧪 **Experience**: 25+ years
🌐 **Languages**: Italian (Native), English (Fluent), German & French (Basic)

💼 EXPERTISE SUMMARY

Veteran Quality Assurance Consultant and Qualified Person with over 25 years of experience across biologics, radiopharmaceuticals, injectables, and drug substances. F. C. has successfully led QA teams, CQV programs, and GMP operations in both large-scale pharma settings and startup environments. Known for driving regulatory inspection readiness, leading process validation, managing batch releases, and optimizing QMS systems in compliance with EMA, FDA, Swissmedic, and ICH standards.

🔧 KEY SKILLS & TECHNOLOGIES

- QP responsibilities for market release & GMP compliance
- Technology transfer, NPI, and process validation
- Deviation handling, CAPA, Change Control (TrackWise, Veeva)
- GMP operations in cleanroom Class A/B/C
- Regulatory readiness (Swissmedic, EMA, FDA, AIFA)
- Software: Kneat, SAP, TrackWise, LIMS, DocuSign

🏭 INDUSTRY EXPERIENCE

- Capgemini: QA Manager for CQV, NPI, and CMO oversight
- Novartis: Senior QA Team Lead & QP for injectable drug products
- Moderna: QA for drug substance validation & Swissmedic inspections
- Air Products: QP for market release of medical gases
- Broad coverage: mammalian cell drug substances, sterile injectables, and radiopharmaceuticals

🎓 EDUCATION

- Qualified Person (QP), Italian Medicines Agency
- PharmD & Master's in Pharmaceutical Chemistry
- Certified in Leadership & Connected Management (Harvard)
- Trainer in risk management, deviation handling & inspection readiness

📈 PROJECT HIGHLIGHTS

- QA CQV Lead at Capgemini: Led deviation reduction initiatives, ECN management, and GMP inspection prep using Kneat, TrackWise & DMS
- Swissmedic Inspection Prep: Managed QA/QC documentation for PPQ activities at a major CMO site
- New Product Launch (NPI): Oversaw QA tech transfer across 4 international CMOs, ensuring full compliance from validation through to regulatory submission
- Novartis QP & QA Lead: Responsible for market batch release and managing multiple global inspections

J. D. P.

QA Consultant | Available now

📍 **Location**: Switzerland (on-site & hybrid projects)
🧪 **Experience**: 20+ years
🌐 **Languages**: Spanish (Native), English (Fluent), German (Basic)

💼 EXPERTISE SUMMARY

J. D. is a seasoned Quality Assurance Consultant and former Qualified Person (QP) with deep-rooted expertise in batch release, packaging, operational quality, and GMP compliance. With a track record spanning over two decades—including senior leadership roles at GSK, Lonza, and Capgemini—J. D. has successfully led cross-functional teams, supported regulatory inspections, and managed deviation and CAPA processes. Their SAP expertise and ability to navigate complex manufacturing and quality systems make them a high-value asset for any pharma operation.

🔧 KEY SKILLS & TECHNOLOGIES

- Batch record review & batch release (Oral Solid Dose, EBR, SAP QM)
- GMP compliance, deviation analysis, CAPA, audit preparation
- Packaging technologies, artwork management, and process efficiency
- Expert in SAP ECC, SAP PP, SAP QM and document workflows
- Hands-on in CQV (CFRs/QFRs), risk assessments, and qualification documentation (Kneat)
- Deep experience with ALCOA+ principles and good documentation practices (GDP)

🏭 INDUSTRY EXPERIENCE

- Capgemini: CQV & QA Consultant (Orca Project, Lonza Visp) – qualification, deviation handling, CFR/QFR review
- Lonza: QA for Bioatrium and Swissmedic inspection readiness – RA, FMEA, and EBR support
- GSK: QP for batch release (2016–2022), QA Operational Lead, and Production Manager (70+ staff)
- CyndeaPharma: Manufacturing lead overseeing process transfer and packaging operations
- Dolisos: QC Responsible – full setup of GMP-compliant quality control lab

🎓 EDUCATION

- Executive MBA – IESE Business School
- Master in Pharmaceutical Industry – CESIF
- Pharmacy Degree – Universidad de Navarra
- SAP SME – SAP ECC, QM, PP
- Trained in Lean Manufacturing, FMEA, SMED, and OEE optimization

📈 PROJECT HIGHLIGHTS

- Swissmedic Readiness (Lonza): Supported RA, CAPA, and SOP readiness ahead of licensing
- Building Validation (Orca Project): Reviewed IQ/OQ documents, incidents, and final reports under GDP and ALCOA+
- SAP SME: Led SAP Manufacturing module integration and process automation for production sites
- Team Leader (GSK): Managed 8-person QA team responsible for documentation and batch certification

CAPEX
Profiles

C. S.

Technical Project Lead & Process Engineer | Available now

📍 **Location**: Switzerland (on-site & hybrid projects)
🧪 **Experience**: 10+ years
🌐 **Languages**: Greek (Native), English (Proficient), German (Basic)

💼 EXPERTISE SUMMARY

C. S. is a dynamic Manufacturing & Process Engineer and Technical Project Lead, with broad experience across pharma production, GMP cleanroom facility design, CAPEX project management, and engineering leadership. He has held end-to-end responsibility for complex projects—ranging from sterile pharma production to large-scale food and dairy facilities—and currently drives technical coordination for a major biologics construction project at Lonza Visp.

🔧 KEY SKILLS & TECHNOLOGIES

- Project management of CAPEX and construction programs in GMP environments
- Hands-on in commissioning, FAT/SAT, validation and handover (cold rooms, clean utilities, packaging lines)
- SAP ERP (BOMs, Routings, Work Centers), AutoCAD, MS Project
- Technical documentation (URS, SOPs, batch records) and regulatory alignment
- Interfacing with QA, QC, engineering, HSE, and cross-functional stakeholders
- Proficient in facility layout design, equipment procurement, and cleanroom standards

🏭 INDUSTRY EXPERIENCE

- Capgemini Engineering @ Lonza: Technical Project Lead for cleanroom and packaging equipment on the ORCA biologics site
- DEMO Pharmaceuticals: Production & Packaging Manager – led 100+ team, ensured cGMP compliance, SAP-driven production planning
- JOTIS Group (Food Industry): Plant Manager, Project Manager, and Process Engineer – spearheaded €20M facility design and digitalization
- Hellenic Petroleum: Supply Chain Optimization Intern – refinery analytics and financial forecasting
- TITAN Cement: Environmental performance & process efficiency project lead

🎓 EDUCATION

- MBA (Part-time) – Athens University of Economics and Business
- MEng in Chemical Engineering (Biotech specialization) – National Technical University of Athens
- Certified in GMP, Lean Manufacturing

📈 PROJECT HIGHLIGHTS

- Lonza ORCA: TPL for cold rooms and CNC environments, coordinating stakeholders across construction, CQV, operations, and QA
- DEMO: Drove productivity and compliance in aseptic manufacturing, led operational excellence initiatives
- JOTIS Group: Delivered complete dairy plant construction and cold storage optimization projects under strict CAPEX control

C. O.

Technical Project Lead | Available now

📍 **Location**: Switzerland (on-site & hybrid projects)
🩹 **Experience**: 10+ years
🌐 **Languages**: English (Native), German (Fluent), French (Proficient), Italian (Intermediate)

💼 EXPERTISE SUMMARY

C. O. is a seasoned Technical Project Lead and Bioprocess Engineer with over a decade of experience in biopharma manufacturing, CAPEX project leadership, and GMP facility commissioning. Currently driving large-scale pharmaceutical infrastructure programs at Lonza, he brings a unique blend of engineering depth and stakeholder leadership to complex manufacturing challenges. His track record includes end-to-end delivery of cleanrooms, single-use systems, reactors, chromatography skids, and modular GMP suites.

🔧 KEY SKILLS & TECHNOLOGIES

- CAPEX project management across biologics, small molecules, and GMP expansion
- Engineering design, equipment specification, FAT/SAT, DQ, IQ, OQ
- Modular cleanroom facility delivery & utilities expansion
- Cross-functional stakeholder engagement & change management
- Proficient with SAP, Kneat Gx, DocuSign, Vector, and Microsoft Office
- Bioreactors, ultrafiltration, diafiltration, solvent systems, wash/autoclaves

🏭 INDUSTRY EXPERIENCE

- Capgemini @ Lonza: Technical Project Lead on major biomanufacturing projects (P2, Apollo, MINT)
- GSK Biopharma: Bioprocess Engineer scaling up vector and cell processing technologies
- GSK Small Molecules: Process Engineer on clinical campaigns and technology transfers
- GEAPower: Environmental Process Engineer on wastewater treatment systems

🎓 EDUCATION

- MEng (Hons) in Chemical Engineering – Loughborough University
- Chartered Member – Institute of Chemical Engineers
- PMP – Project Management Professional Certified
- Exchange Research Program – University of Oulu, Finland

📈 PROJECT HIGHLIGHTS

- Delivered a GMP modular clean manufacturing building, managing design, execution, and qualification
- Technical lead on high-potency reactor/isolator, chromatography skids, solvent distribution, and thawing suites
- Led cross-functional teams and acted as key liaison with external suppliers and internal QA, QC, and MSAT
- Managed a team of 9 Capgemini consultants and provided coaching, performance reviews, and development plans

D. B.

Senior Project Engineer | Available now

📍 **Location**: Switzerland (on-site & hybrid projects)
🧪 **Experience**: 15+ years
🌐 **Languages**: English (Fluent), French (Native)

💼 EXPERTISE SUMMARY

Senior Manufacturing & Process Engineer with a strong track record in project management (PMO), GMP compliance, and process equipment qualification for top life sciences companies. Over the past 15+ years, he has contributed to successful biotech and pharma projects at Merck, Novartis, Biogen, and Celgene, from design and commissioning to validation and compliance. His technical depth is complemented by hands-on experience with TrackWise, MS Project, and FMEA methodology.

🔧 KEY SKILLS & TECHNOLOGIES

- Project Management (500K+ CHF budgets)
- Equipment design, FAT/SAT, IQ/OQ/PQ
- Risk analysis (FMEA), validation protocols
- QA complaint & deviation handling
- MS Project, Honeywell TrackWise
- PMO leadership across biotech, medical devices, and pharma

🏭 INDUSTRY EXPERIENCE

- Merck Serono (2017–2025): Led biotech process optimization, new equipment design, validation strategy, and deviation management (TrackWise)
- Novartis (2016–2017): Managed production of drug substance and drug product for clinical trials on the Basel main campus
- Biogen (2015–2016): QA engineer handling complaint management
- Dentsply (2013–2014): QA Engineer managing Critical Control Points
- Nestlé Health Science (2012–2013): Project Engineer developing medical devices
- Celgene (2012): QA Engineer managing GMP complaints
- Medtronic (2011): Full equipment lifecycle management and validation lead
-

🎓 EDUCATION

- Chemical Engineer – School of Fribourg
- Certified Laborant en chimie
- Proficient in FMECA, protocol drafting, and compliance systems (TrackWise, CAPA workflows)

📈 PROJECT HIGHLIGHTS

- Spearheaded the qualification of biotech equipment and compliance efforts for a multi-year GMP project at Merck
- Designed and managed risk-based validation strategies and trained teams on validation practices
- Drove cross-functional collaboration between QA, engineering, and operations for process improvement initiatives

M. U.

Manufacturing & Process Engineer | Available now

📍 **Location**: Europe (on-site & hybrid projects)
🧪 **Experience**: 5+ years
🌐 **Languages**: English (Fluent), French (Basic)

💼 EXPERTISE SUMMARY

Versatile Manufacturing & Process Engineer with strong expertise in project management, GMP compliance, and process optimization in highly regulated environments. With experience in both pharma (ROVI, Becton Dickinson)and chemical industries (Budenheim), she excels at managing end-to-end technical projects from design to qualification. She brings a data-driven mindset and Lean Manufacturing know-how, enabling her to deliver impactful solutions across commissioning, maintenance, and sterilization processes.

🔧 KEY SKILLS & TECHNOLOGIES

- Full project lifecycle: URS to PQ
- GMP compliance & documentation control
- Process validation: EO sterilization, equipment setup
- Lean Six Sigma Green Belt – process improvement, SPC
- Budget and KPI monitoring, risk mitigation
- SAP (PM Module), FMEA, P&ID review

🏭 INDUSTRY EXPERIENCE

- ROVI Pharma (2024–2025): Led technical projects across multiple departments, coordinated contractor activities, and reviewed all GMP documentation for commissioning and qualification phases
- Becton Dickinson (2021–2023): Managed EO sterilization process improvement, performed KPI tracking, and executed preventive maintenance planning for cost reduction
- Budenheim (2021): Structured a preventive maintenance system and oversaw technical documentation and cost modeling for overhaul planning

🎓 EDUCATION

- Master's Degree in Industrial Engineering – Escuela de Ingeniería y Arquitectura, Universidad de Zaragoza
- Bachelor's Degree in Mechanical Engineering – Escuela de Ingeniería y Arquitectura, Universidad de Zaragoza

📈 PROJECT HIGHLIGHTS

- Built a preventive maintenance database integrating asset criticality and frequency to optimize downtime and budget
- Led documentation and validation activities (URS, FAT/SAT, IQ/OQ/PQ) across multiple projects
- Coordinated "what-if" scenario testing and change control planning for facility upgrades
- Ensured process robustness for EO sterilization aligned with ISO 11135 and TIR15

N. D.

Manufacturing & Process Engineer | Available now

📍 **Location**: Switzerland (on-site & hybrid projects)
🧪 **Experience**: 8+ years
🌐 **Languages**: Greek (Native), English (Fluent), German (Proficient)

💼 EXPERTISE SUMMARY

Highly skilled Biomedical and Process Engineer with extensive experience across the pharmaceutical and medical device industries. With a PhD in Biomedical Engineering and deep expertise in tech transfer, CQV, and cleanroom facility design, she has supported complex greenfield projects involving APIs, biologics, and drug product manufacturing. Her multidisciplinary background allows her to bridge engineering, validation, and GMP compliance with innovation and precision. N. D. excels in cross-functional settings and brings a research-driven mindset to continuous improvement initiatives.

🔧 KEY SKILLS & TECHNOLOGIES

- Aseptic manufacturing, process validation, and cleanroom facility design
- Equipment URS, P&ID review, risk analysis, and Design Qualification
- Tech transfer, gap analysis, and change control execution
- Commissioning, Qualification & Validation (IQ, OQ, PQ)
- 3D CAD & 3D printing for device prototyping and design iterations
- GMP compliance, ALCOA principles, ISO 13485, ISO 14644, ISO 14971
- Tools: Aspen HYSYS, AutoCAD, COMSOL, Kneat Gx, Minitab, Python

🏭 INDUSTRY EXPERIENCE

- Capgemini @ Lonza – CQV Team Lead for clean utilities and process systems commissioning
- FAMAR S.A. – Process Engineer for sterile drug product transfers and validation documentation
- DEMO SA – Project & Process Engineer for biopharma plant layouts and equipment specification
- Hellenic Army – Chemical Engineer in anti-freeze production unit

NTUA Research Lab – Researcher in medical device design and drug delivery modeling

🎓 EDUCATION

- PhD in Biomedical Engineering – National Technical University of Athens
- MSc in Services Management – Athens University of Economics and Business
- Diploma (MEng equivalent) in Chemical Engineering – NTUA
- Erasmus Program – Technical University of Berlin
- Lean Six Sigma Yellow Belt – Technical University of Munich
-

📈 PROJECT HIGHLIGHTS

- Led CQV activities at Lonza for clean utility systems, authoring GDP-compliant documentation
- Directed process tech transfer and validation of eye/ear drops and injectables at Famar
- Designed layouts and material flows for multiple greenfield facilities producing biologics and APIs
- Developed PoC medical devices using CAD modeling and 3D printing for islet encapsulation
- Supervised master students and delivered lectures on process design and chemical industries

P. B.

Consultant Process & Manufacturing Engineer | Available now

📍 **Location**: Switzerland (on-site & hybrid projects)
🧪 **Experience**: 6+ years
🌐 **Languages**: English (Fluent)

💼 EXPERTISE SUMMARY

P. B. is a versatile Process and Mechanical Engineer with over six years of hands-on experience delivering complex projects in the pharmaceutical, biotechnology, and food industries. From greenfield biopharma plants to sustainable whiskey distilleries, P. B. has led the design and execution of critical process and utility systems, covering everything from water purification to aseptic isolators and bioreactors. With a strong foundation in front-end engineering, vendor and contractor management, and CQV, he brings value through a holistic, sustainability-conscious approach.

🔧 KEY SKILLS & TECHNOLOGIES

- Conceptual & detailed design for pharmaceutical and life sciences facilities
- Front-end studies, process & utility equipment specification, vendor selection
- Package ownership: Purified Water, Clean Steam, Bioreactors, CIP/SIP, Labelers
- Construction supervision, cost management, and commissioning readiness
- Specialist in Life Cycle Assessment (LCA) for sustainable construction
- Tools: Abaqus/CAE, Siemens STAR-CCM+, SolidWorks | Standards: GxP, FDA, ASME

🏭 INDUSTRY EXPERIENCE

- Capgemini Engineering (2025 – current):
- Consultant Process & Manufacturing Engineer – supporting life sciences facility design and execution across Europe.
- PM Group (2021 – 2025): MSD, Netherlands: Utility Package Owner for inactivated vaccines and antibiotics site
- Irish Distillers: Expansion of alcohol spirit storage & large-scale brownfield utility plant
- Bayer, USA: Process Equipment Package Owner for allogenic cell therapy project
- Pfizer, Ireland: Design for API production during COVID-19 scale-up
-

🎓 EDUCATION

- Masters in Mechanical Engineering – University of Limerick
- Commissioning, Qualification & Validation for Biologics Manufacturing – Atlantic Technical University
- Construction Life Cycle Assessment Specialist – OneClick LCA
- Environmental, Sustainability and Climate Studies – University College Cork

📈 PROJECT HIGHLIGHTS

- Delivered major brownfield retrofits in vaccine and cell therapy facilities with high GMP compliance
- Led the design and installation of bioprocess equipment including Wave Bioreactors and Cell Stack Manipulators
- Served as Mechanical Sustainability Champion at PM Group
- Delivered purified water and clean utility systems under urgent COVID production timelines
- Developed detailed LCA models for sustainable engineering projects

Meet our experts.
Partner with Capgemini.

At Capgemini, our people are the engine behind our innovation. From tech transfer to CQV, from sustainability-driven design to GMP manufacturing excellence, our consultants bring deep expertise, hands-on execution, and a collaborative mindset to every project.
Whether you're building the factory of the future or accelerating regulatory compliance, our team is ready to deliver measurable impact — from strategy to implementation.

Let’s build the future of life sciences, together.

✉️ Contact us: communications.ch@capgemini.com
🌐 Learn more: landing page URL

Capgemini